Iroko Pharmaceuticals Announces Acceptance for NDA Filing of Lower Dose Submicron Indomethacin for the Treatment of Mild to Moderate Acute Pain in Adults

Second NDA Filing Acceptance from Iroko's Submicron NSAID Pipeline

PHILADELPHIA, July 16, 2013 — **Iroko Pharmaceuticals, LLC**, a global specialty pharmaceutical company dedicated to scientific advancements in analgesia, announced that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for lower dose submicron indomethacin, a non-steroidal anti-inflammatory drug (NSAID), for the proposed indication of treatment of mild to moderate acute pain in adults. This is the second NDA filing from Iroko's submicron NSAID pipeline to be accepted by FDA in 2013.

"FDA's acceptance of our NDA filing for submicron indomethacin provides further momentum to our submicron NSAID strategy," said Osagie Imasogie, Chairman of Iroko Pharmaceuticals. "Indomethacin is a drug with potent anti-inflammatory and analgesic properties. By developing a lower dose indomethacin, we aim to provide a new option for acute pain management. We look forward to working closely with FDA during the review process."

Iroko is developing lower dose submicron NSAIDs, using proprietary SoluMatrix™ technology, designed to provide effective pain relief at lower doses than existing commercially-available NSAIDs. In February 2013, FDA accepted the NDA filing for lower dose submicron diclofenac for the treatment of mild to moderate acute pain in adults.

The NDA submission for lower dose submicron indomethacin included data from two Phase 3 multicenter, randomized, double-blind, controlled trials in 835 patients with acute pain following surgery. The trials were designed to compare the analgesic efficacy of the active treatment groups with placebo. Data from one of the studies were recently presented at the 29th Annual Meeting of the American Academy of Pain Medicine (AAPM) in Fort Lauderdale, Florida in April 2013.

About Lower Dose Submicron NSAIDs

The risk of adverse events, including upper gastrointestinal ulcers[3], gastrointestinal bleeds[1], and cardiovascular events[2] associated with currently marketed NSAIDs is higher among patients receiving higher doses of NSAIDs[3]. Iroko is at the forefront of the development of lower dose submicron NSAIDs – new drug products based on existing NSAIDs – that are designed to potentially provide effective pain relief at lower doses than existing commercially available oral drug products. These lower dose submicron NSAIDs are being developed by Iroko, using iCeutica Pty Ltd's proprietary SoluMatrix™ technology, licensed to Iroko for exclusive use in NSAIDs. The SoluMatrix™ technology alters the pharmacokinetic absorption properties of NSAIDs by reducing drug particles to finer particles that are at least 10 times smaller than standard oral NSAID formulations, thereby enhancing drug dissolution and promoting absorption.

About Iroko Pharmaceuticals, LLC

Iroko is a global specialty pharmaceutical company, based in Philadelphia, dedicated to scientific advancements in analgesia. The company acquires, develops and globally commercializes currently marketed products. In addition to the Iroko products that are marketed worldwide, the company has a robust pipeline of late-stage submicron NSAID product candidates using the proprietary SoluMatrix™ platform. These submicron NSAIDs are being developed using iCeutica Pty Ltd's SoluMatrix™ technology, licensed to Iroko for exclusive use in NSAIDs. For more information, visit **www.iroko.com**.

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[1] Rahme E et. al. (2001 Aug). Cost of prescribed NSAID-related gastrointestinal adverse events in elderly patients. Br J Clin Pharmacol. 52(2): 185-192.
[2] Howes LG. (2007 Oct). Selective COX-2 inhibitors, NSAIDs and cardiovascular events – is celecoxib the safest choice? Ther Clin Risk Manag, 3(5), 831-845.
[3] Risser A. (2009 Dec). NSAID Prescribing Precautions. Am Fam Physician. 80(12):1371-1378.